


performed by Dr. Burns using an ultrasonic diagnostic system prepared for Dr. Burns under the direction of Dr. Powers. As explained therein this ultrasound system has a probe which transmits fundamental frequency signals and receives harmonic signals which are separated by means of a programmable digital filter in the ultrasound system. The separated harmonic signals are detected and displayed as images on the system monitor. Prints of these harmonic images are included in the report. The report demonstrates conception and reduction to practice of the claimed invention in January, 1992, over four years before the filing of the Hossack '128 patent. It is therefore respectfully submitted that the Hossack '128 patent is properly withdrawn as a reference in this case.

Claims 13-18 as amended were determined to be patentable over the art of record with detailed consideration given to the Porter '364 patent, and the recognition that the Rafter et al. '281 patent is of ineffective date in this case by reason of applicants' October 10, 1995 priority date.

Claim 24 was determined to be patentable over the art of record.

Claim 26 has been amended to more clearly define the present invention. Amended Claim 26 describes a two pulse technique whereby undesired tissue echoes are eliminated from desired microbubble responses by means of their differing response characteristics following incoherent detection. This is distinctly different from the pulse inversion technique of Hwang et al. (5,706,819) and the Chapman (5,632,277) and Fink (5,010,885) patents. In pulse inversion, oppositely phased transmit pulses result in signals which can be combined to separate harmonic and fundamental frequency signals on the basis of the quadratic nature of harmonics. Claim 26 is also distinctly different from the concept of the Johnson et al. '257 patent, which uses a two pulse technique to detect microbubbles by detecting their presence and absence following successive pulses. In neither case are tissue and contrast echoes separated from each other on the basis of their differing response characteristics following incoherent detection. As Fig. 17 of the case demonstrates, this technique is useful for detecting contrast agent perfusion of the heart muscle (myocardium) in the presence of unwanted tissue echoes returning from the pericardium. The tissue echoes, being of a different sense following incoherent detection, can simply be clipped by thresholding, for instance. Accordingly it is respectfully submitted that Claims 26-29 as amended are patentable over Hwang et al., Chapman, Fink, Johnson et al. and the other art of record.



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Claims 30-36 were determined to be patentable over the art of record by virtue of their recitation of the use of high and low energy ultrasonic pulses, a contrast signal processor and a B mode signal processor pending a final review of U.S. Pats. 5,456,255 (Abe et al.), 5,469,849 (Sasaki et al.), 5,628,322 (Mine et al.) and 5,724,976 (Mine et al.)

In light of the foregoing cancellation of Claims 19-23 and 25, the amendment to Claims 13 and 26, and the showing of prior invention by the enclosed declaration, it is respectfully submitted that Claims 1-18, 24, and 26-38 are in condition for allowance. Favorable consideration is respectfully requested.

Respectfully submitted,
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PATENTABILITY

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Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). <

As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore*, 439 F.2d 1232, >1236, < 169 USPQ 236>, 239< (CCPA 1971).

The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.

How a teaching is set forth, by specific example or broad terminology, is not important. *In re Marzocchi*, 439 F.2d 220, >223-24< 169 USPQ 367 >, 370< (CCPA 1971). A rejection of a claim under >35 U.S.C. < 112 as broader than the enabling disclosure is a first paragraph enablement rejection and not a second paragraph definiteness rejection. Claims are not rejected as **>broader than the enabling disclosure< under 35 U.S.C. 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801, >806, < 166 USPQ 85>, 88< (CCPA 1970). > One does not look to the claims but to the specification to find out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-17 (Fed. Cir. 1983); *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977). In *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976), the Court stated:

to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his

claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification. "That claims are interpreted in light of the specification does not mean that everything in the specification must be read into the claims." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984).

The record must be clear so that the public will have notice as to the patentee's scope of protection when the patent issues. If a reasonable interpretation of the claim is broader than the description in the specification, it is necessary for the examiner to make sure the full scope of the claim is enabled. Limitations and examples in the specification do not generally limit what is covered by the claims.

The breadth of the claims was a factor considered in *Amgen v. Chugai Pharm. Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991). In the *Amgen* case, the patent claims were directed to a purified DNA sequence encoding polypeptides which are analogs of erythropoietin (EPO). The Court stated that:

Amgen has not enabled preparation of DNA sequences sufficient to support its all-encompassing claims. . . . [D]espite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. . . . This disclosure might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

927 F.2d at 1213-14, 18 USPQ2d at 1027. However, when claims are directed to any purified and isolated DNA sequence encoding a specifically named protein where the protein has a specifically identified sequence, a rejection of the claims as broader than the enabling disclosure is generally not appropriate because one skilled in the art could readily determine any one of the claimed embodiments.

See also *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993) (The evidence did not show that a skilled artisan would have been able to carry out the steps required to practice the full scope of claims which